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Name	Registration No (if applicable)
<u>Linda S. Jernigan</u>	
October 27, 2004	Signature
Date	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/810,358  
Applicant(s) : Chen et al.  
Filed : March 26, 2004  
Title : Methods Of Determining Efficacy Of Treatments  
Of Diseases Of The Bowel  
TC/A.U. : 1616  
Examiner :  
Conf. No. : 1244  
Docket No. : 9188R&  
Customer No. : 27752

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. [ ] 37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2.  37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). An Office Action on the merits in the present application has not yet been received. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3.  37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). A first Office Action after filing a Request For Continued Examination (RCE) has not yet been received. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4.  37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). A final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) has not been received as of the date of this submission. I hereby elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5.  Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case). This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

- (1) (For use with applications filed prior to or on June 30, 2003.) Copies of the cited documents are enclosed.

OR

- (2) (For use with applications filed after June 30, 2003.) In accordance with 37 C.F.R. §1.98(a)(2), copies of only foreign patent documents and non-patent literature are enclosed.

OR

- (3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. \_\_\_\_, U.S. Patent Application Serial No. \_\_\_, filed \_\_\_. Priority is claimed to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR

- (4) Copies of all said documents, except Cite Numbers \_\_\_\_\_, were submitted and considered in parent application U.S. Patent Application Serial No. \_\_\_\_\_, filed \_\_\_\_\_. Priority is claimed to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

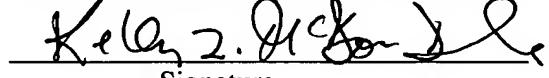
- (5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

(6) It is respectfully requested that the Examiner consider and make of record the co-pending applications listed on the attached page.

Additional information attached is generated from the International Search Report.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY



Signature

Kelly L. McDow-Dunham

Typed or printed name

Registration No. 43,787

(513) 622-0159

Date: October 27, 2004

**Customer No. 27752**

(9188R& Suppl. IDS.doc) (Last Revised 10/06/2004)

Please type a plus sign (+) inside this box → [+]

SUPPL. PTO/SB08A (08-03)

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Substitute for form 1449A/PTO

COMPLETE IF KNOWN	
Application Number	10/810,358
Confirmation Number	1244
Filing Date	March 26, 2004
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	9188R&

## INFORMATION DISCLOSURE STATEMENT BY ~~APPLICANT~~

(use as many sheets as necessary)

SHEET 1 of 2

## U. S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 37 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>	<p><b>COMPLETE IF KNOWN</b></p>
	Application Number <b>10/810,358</b>
	Confirmation Number <b>1244</b>
	Filing Date <b>March 26, 2004</b>
	First Named Inventor <b>Chen et al.</b>
	Group Art Unit <b>1616</b>
	Examiner Name <b></b>
	Attorney Docket Number <b>9188R&amp;</b>

## NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	CITE NO. <sup>1</sup>	INCLUDE NAME OF THE AUTHOR (IN CAPITAL LETTERS), TITLE OF THE ARTICLE (WHEN APPROPRIATE), TITLE OF THE ITEM (BOOK, MAGAZINE, JOURNAL, SERIAL, SYMPOSIUM, CATALOG, ETC.), DATE, PAGE(S), VOLUME-ISSUE NUMBER(S), PUBLISHER, CITY AND/OR COUNTRY WHERE PUBLISHED	T <sup>2</sup>
	4	HILDESHEIM ET AL., "Simultaneous Measurement Of Several Cytokines Using Small Volumes Of Biospecimens", <u>Cancer Epidemiology, Biomarkers &amp; Prevention</u> , Vol. 11, pgs. 1477-1484, November 2002, XP002296946 abstract	
	5	ANDUS ET AL., "Imbalance Of The Interleukin 1 System In Colonic Mucosa – Association With Intestinal Inflammation And Interleukin 1 Receptor Agonist Genotype 2", <u>Gut</u> , Vol. 41, 1997, pages 651-657, page 654, column 2-page 655, column 1 figure 2D, XP002296947	
	6	ROGLER ET AL., "Cytokines In Inflammatory Bowel Disease", <u>World Journal of Surgery</u> , Vol. 22, 1998, pages 382-389, XP002296948 the whole document	
	7	O'CALLAGHAN ET AL., "Human Cytokine Production By Mesenteric Lymph Node Cells In Response To Probiotic And Pathogenic Bacteria", <u>Gastroenterology</u> , Vol. 122, No. 4 Suppl. 1, page A-151 DDW Meeting Abstract Nr. S1040, April 2002, XP009036734 the whole document	
	8	MCCARTHY ET AL., "Double Blind, Placebo Controlled Trial Of Two Probiotic Strains In Interleukin 10 Knockout Mice And Mechanistic Link With Cytokine Balance", <u>Gastroenterology</u> , Vol. 122, Nr. 4 Suppl. 1, pages A-389-A390 DDW Meeting Abstract Nr. T962, XP009036733 the whole document	
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.**

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